K032307 1 of 2

CONFIDENTIAL

OCT 2 4 2003

SUMMARY OF SAFETY AND EFFECTIVENESS

SPONSOR:	ETEX Corporation 38 Sidney Street, 3rd Floor Cambridge, MA 02139 Phone: (617) 577-7270 x236 Fax: (617) 577-7170
510(k) CONTACT:	Kristine Canavan Manager, Regulatory Affairs
TRADE NAME:	CaP Bone Substitute Material
COMMON NAME:	Bone Graft Material Bone Substitute Material
CLASSIFICATION:	Class II
CLASSIFICATION NAME:	21 CFR 882.5300
	Methyl Methacrylate for Cranioplasty
PRODUCT CODE:	87 GXP
PREDICATE DEVICES:	a-BSM® Bone Substitute Material 510(k) No.: K983009, ETEX Corporation

DEVICE DESCRIPTION:

Calcium Phosphate (CaP) Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. It is intended for use in cranial-maxillo-facial surgical repair applications. At the time of use, the CaP product material is combined with the mixing liquid (U.S.P. Sodium Chloride, 0.9%) in the elastomeric mixing bulb, and is mixed, using a kneading technique, to form a paste. The paste can be administered to the treatment site by manual application, and be shaped *in situ* or into a desired form prior to implantation. After applying the

paste to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly crystalline hydroxyapatite (PCHA), is of low crystalline order and has a similar chemical identity and crystalline structure to that of natural bone. CaP Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

INDICATIONS FOR USE:

CaP Bone Substitute Material is an implantable bone graft, that is a synthetic, calcium phosphate, hydroxyapatite material intended for use in the filling, repair, reconstruction and augmentation of burr holes, contiguous craniotomy cuts, and other defects in craniofacial bones including fronto-orbital, malar and mental areas, with a surface area no larger than $25cm^2$.

BASIS OF SUBSTANTIAL EQUIVALENCE:

CaP Bone Substitute Material is a synthetic bone graft substitute material substantially equivalent to α-BSM Bone Substitute Material (OMF). Both materials are provided sterile and as single patient, single use kits and are identical in intended use (i.e., cranio-maxillo-facial indications). CaP Bone Substitute Material is also similar to α-BSM Bone Substitute Material (OMF) in material properties and in product performance characteristics. Differences between the CaP and α-BSM products do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 24 2003

Ms. Kristine Canavan
Manager, Regulatory Affairs
ETEX Corporation
University Park at MIT
38 Sidney Street
Cambridge, MA 02139

Re: K032307
Trade Name: CaP Bone Substitute Material
Regulation Number: 21 CFR 882.5300
Regulation Name: Methyl Methacrylate for Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: July 24, 2003
Received: July 28, 2003

Dear Ms. Canavan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Millerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K032307

Device Name: CaP Bone Substitute Material

Indications for Use:

CaP Bone Substitute Material is an implantable bone graft, that is a synthetic calcium phosphate hydroxyapatitic material intended to be implanted for use in the filling, repair, reconstruction and augmentation of burr holes, contiguous craniotomy cuts, and other defects in craniofacial bones including fronto-orbital, malar and mental areas with a surface area no larger than $25cm^2$.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use

(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K03 2307